DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 23 1988

Re: Ucephan
Docket No. 88E-0104

SOLICITOR

MAR 28 1988

U S PATENT &
TRADEMARK OFFICE

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,284,647 filed by Kendall-McGaw Laboratories, Inc. under the patent term extension provisions of 35 U.S.C. 156. The human drug product claimed by the patent is Ucephan (sodium phenylacetate and sodium benzoate), New Drug Application (NDA) 19-530.

A review of the Food and Drug Administration's official records indicates that Ucephan, the product identified in the patent term extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the active ingredients, sodium phenylacetate and sodium benzoate.

Our records also indicate that NDA 19-530 was approved on December 23, 1987. Since the last day of the applicant's 60-day period for filing for patent term extension fell on Saturday, February 20, 1988, the submission of the patent term restoration application received on the next business day, February 22, 1988, 62 days after NDA approval, nevertheless meets the requirements of timeliness within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Donald J. Bird
Cushman, Darby and Cushman
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